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Breaking the Fence: Can Patent Rights Deter Biomedical Innovation in 'Technology Followers'?

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ABSTRACT *The impact of patent protection on biomedical innovation has been a controversial issue. Although a 'medical anti-commons' has been predicted as a result of a proliferation of patents on upstream technologies, evidence to test these concerns is only now emerging. However, most industrial surveys that shed light on this issue are mainly from developed countries, making it very difficult to predict the impact of patenting on biomedical innovation in developing and least developed countries. This paper develops a framework of analysis for the impact of patent rights on biomedical innovation in 'technology follower' developing countries. Based on the framework developed in the paper, empirical data collected in an industry-level survey of the Indian pharmaceutical industry between November 2004 and January 2005 is used to analyze the impact of patent rights as recognized under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) on biomedical innovation in technology followers.*

KEY WORDS:

1. Introduction

Firms rely on a variety of appropriability mechanisms to protect their innovations, such as secrecy and first mover advantages, which are often more important than patents.[1] But the choice of appropriability mechanisms depends very much on the sector and in the pharmaceutical sector; patents are a very important instrument for the protection of innovations.[2] Over time, stronger patent regimes, newer technologies such as biotechnology and changing industrial structures have contributed to an increased proliferation of patents in the biomedical sector.[3]

Therefore, not surprisingly, the issue how intellectual property protection as contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement) will impact biomedical innovation is a controversial one, with claims in either direction. A medical 'anti-commons' was predicted following a dramatic increase in patenting activity especially in the pharmaceutical and biotechnological sectors in the early 1990s.[4] It has been argued that present levels of intellectual property protection lead to too many

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patent rights on upstream discoveries in biomedical research and have the potential to stifle downstream discoveries and product development by increasing transaction costs and magnifying the risk of failures.[5] According to scholars, this problem is worsened by patent scope issues that grant too broad claims to early innovators, thereby making it necessary on subsequent innovators to procure licenses on research tools or earlier innovations to conduct R&D, or even limit them from fully capturing the gains of their innovations.[6] The World Health Organization has classified these detrimental impacts of patents on access to research tools[7] in the biomedical sector into three major categories: increasing the costs of available services, imposing transaction costs and inconveniences on R&D and impeding the transfer of existing tools and technologies.[8]

Whether intellectual property rights (hereafter, IPRs) create an anti-commons or lead to restricted access to research tools is a highly complex question. This not only involves considerations of broader patent scope and its impact on innovation, but also, effects of IPRs (as we have them now) on stimulating R&D, bargaining anomalies that may result from monopolistic positions, information issues and transaction costs,[9] and most importantly, social costs imposed by grant of such a patents regime – that is, whether there are innovation projects under this regime that were not undertaken owing to IPR issues under a TRIPS-compliant regime, and if so, do the other benefits of granting such IPRs offset these costs/losses? Many of these issues have been dealt with in the literature on the topic, but mainly from a developed country perspective and in a framework that predominantly considers the needs and characteristics of biomedical innovation in developed countries. The evidence to test the relationship between patents and biomedical innovation, although scanty, is also only available from select developed countries.

Although it has been clearly acknowledged that there is a need to look at the implications of the TRIPS Agreement on innovation and development, a coherent framework to do so is yet to emerge. The implications of a global IPR framework such as the TRIPS Agreement may be varied for countries at different stages of development, and this may have the effect of separating the countries across regions (North vs South in the most basic sense), and also affect the process of catching up.[10] In this context, this paper argues that this topic assumes at least as much importance if not more, in technology follower developing countries that are trying to/have been able to develop significant local innovative capacity in the biomedical sector. Specifically, what may look like a benign hindrance in the case of developed countries with significantly advanced biomedical sectors may in fact turn out to be a major deterrent in the case of a technology follower country where firms routinely experience difficulties in building technological capabilities in biomedical sciences. Other differences in the local innovation context may also have an impact on how IPRs on biomedical products affect innovation trends. Mainly because of this, the paper also considers the issues in terms of technology follower countries, rather than technology follower firms, although the results may be equally applicable to technology follower firms in developed countries as well.

Three main issues seem to be of utmost importance for technology follower countries: (a) Can accumulated IPR positions by firms in developed countries that have a lead technological advantage be used to prevent serious competition from industries in developing countries in innovative activities at the frontier? (b) What sort of bargaining anomalies could result from monopolistic positions, information issues and transaction costs when one talks of licensing arrangements between firms across the globe? (c) How important are the restrictions placed by such IPRs when compared to other factors that affect firm-level decisions on taking up new innovation projects?

This paper seeks to make a contribution towards analyzing the impact of patent protection on biomedical innovation in developing countries in two ways – by identifying the main issues that call for a separate framework for assessing the impact of intellectual property rights on biomedical innovation in these countries, and by presenting evidence from the Indian pharmaceutical industry on this issue. Based on empirical data that was collected in 2004–2005 as part of a firm level survey of the Indian pharmaceutical industry, the paper seeks to draw robust conclusions on the impact of patents when compared to other factors that impede/facilitate innovative capabilities in the biomedical sector.

For purposes of this paper, the term 'technology followers' refers to developing countries with newly industrializing sectors where the technological frontiers do not represent the 'state-of-the-art' technology in the field.[11] As against a static definition of 'technology followers', the definition considered in this paper is more dynamic and assumes that whereas the newly industrializing sector as a whole may not be involved in 'state-of-the-art' innovation; individual firms therein are capable of offering competition in innovative activities at the global technological frontier. Innovation is defined from the view point of the firm, to essentially comprise of the practice and production of all product and process technologies that are new to them and their context and not necessarily to the universe.[12] All activities at the firm level that enhance learning skills, expand the knowledge base and increase competitiveness both locally and globally, are innovative activities. R&D is one form of knowledge production, but such a definition includes also all other forms of activities through which firms access knowledge and technologies in order to progress along the learning curve. Thus, any sector at any given point of time has firms ranging between those that perform innovative activities at the global frontier, to others that are innovating not at the frontier, but are involved in a constant, dynamic process of technological learning to move to the frontier. Biomedical innovation is defined as pharmaceutical innovation that has integrated modern biotechnological processes into its domain, whether for research or the development of products.[13] Research tools are defined as 'any tangible or informational input into the process of discovering a drug or any other medical therapy or method of diagnosing a disease'.[14] In the analysis, newer innovation projects are taken as opportunities of building innovative capabilities. From a dynamic perspective, the more a firm is compelled to abandon useful innovation projects because of IPR restrictions, the larger the probability that the expansion of its technological capabilities are restricted.

2. Intellectual Property Rights and Biomedical Innovation in Developing Countries: A Framework for Analysis

In neoclassical economics, patents are a solution for the market failure caused by the non-excludability and non-rivaled nature of information as a good.[15] Traditionally, the static costs of patents on competition and diffusion of information are off-set by their dynamic impact on incentives to innovate. Hence, design of optimal patent regimes comprises an assessment of the links between patent characteristics (patent length and patent scope), firm profits, and incentives to innovate.[16] Simply put, one can assume that the longer the patent life, the greater the expected rents and the broader the patent scope, the greater the market power that is conferred on the patent holder.[17] Patent breadth/scope, however, is defined as 'how similar other innovations can be without infringing the original patent'.[18] Patent scope determines the strength of protection granted and therefore also the extent of power vested in the patent holder to limit competition. Restricting the scope of protection has

151 therefore been seen as a way of balancing the static costs of intellectual property protection as against the dynamic gains of encouraging innovative activity.[19] Similarly, diffusion of useful information that forms the basis of the patent is to be achieved by placing certain limitations on patent height (level of disclosure required in a patent application for the grant of a patent) within patent regimes.

156

2.1. Motives for Patenting

Recent evidence generated by industry surveys reveals that as against the market failure argument postulated by neoclassical economics for grant of patents, a variety of strategic
161 motives prompt the use of patents as an appropriability mechanism by firms today. These 'strategic motives' include the use of patents as negotiating levers, tools for prevention of infringement suits or block innovations from competitors, to capture extra value for innovative efforts, among others. Excess market power accumulated through patents is used by firms to control diffusion of inventions and research results[20] and/or to cover entire areas
166 of research or preserve market shares by accumulating 'sleeping patents' that help capture extra value for innovative efforts.[21] A comparative survey of the manufacturing sectors in USA and Japan[22] found strategic uses of patents to be common in the manufacturing sectors in both countries, with a higher prevalence of the same in Japan.[23] The electronics industry is also a fertile example of strategic patenting.[24]

171 In biomedical innovation too, patents are used for a variety of strategic reasons. Thumm notes from the results of a survey of the Swiss biotechnology industry that apart from protecting one's own technology from imitation, the second most prominent motive of firms to apply for a patent was to prevent competitors' patenting and application activities.[25] The survey also found that the fourth most prominent motive to patent was to improve the firm's
176 situation in R&D cooperation.[26] Strategic use of patenting by firms is encouraged by patent policies that lay an emphasis on enhanced patenting activity in the biomedical sector and also grant increased patent scope (and encourage broader claims), thereby leading to a situation where there are more patents per products/technology. This creates scope for proliferation of patents on upstream discoveries that can have the effect of stifling newer innovations. In
181 one of the first papers on this topic, Heller and Eisenberg made the point that the greater the number of patent holders that need to be brought into agreement for any downstream discovery to proceed, the greater the risk that bargaining anomalies caused by transaction cost issues will prevent this from happening, thereby causing a 'tragedy of the anti-commons'.[27]

Up until now, concerns raised in the IPRs-biomedical innovation nexus have mainly
186 been prompted by several characteristics of biomedical innovation in developed countries. Legislative initiatives such as the American Bayh–Dole Act of 1980 meant to encourage patenting in academic research have not only expanded the kinds of institutions that claim patent rights on biomedical innovations, but also encouraged the patenting of early-stage discoveries that result from publicly-funded research and are considerably removed from
191 final product development.[28] The emergence of biotechnology start-ups have blurred the boundaries between academic research and commercial entrepreneurship, and at the same time, expanded the limits of patenting in biomedical research even further. The predominance of private research over public-funded research in biosciences is yet another factor that has led to a larger amount of research results being covered by proprietary claims.[29]
196 Therefore, IPRs might not only hinder firm–firm interactions, but also firm–academia or even academia–academia interactions in biomedical research.[30]

2.2. Bargaining and transaction cost issues

Biomedical innovation is characterized by the flow of ideas, skills and research tools between universities, research institutes and the private sector and transaction costs arise due to institutional heterogeneity and conflicting agendas of the different agents, difficulties in valuation of tools and associated information and increased litigation.[31] Information asymmetries on the value of patented tools as research inputs cause difficulties in evaluation and lead to undue expectation of rents from the transaction.[32] More generally, research tool users feel that the provider is asking for too much in return for access to a patented product based on an over-valuation of the contribution of the tool relative to other inputs for future valuable discoveries. Such factors create situations that increase costs of bargaining for research tools and hinder meaningful exchange; and rather seem to point out to how patents can be used strategically to block research.[33] As Cohen *et al.* appropriately note: 'Patents become weapons in mutually reinforcing, non-cooperative strategic interactions where firms feel increasingly compelled to patent either because they need to protect themselves from suits or from being blocked, or they want to block rivals or use patents as bargaining chips in negotiations'.[34] The transaction costs of patents on research tools can go well beyond bargaining, into specific forms of commercialization hurdles.[35] Patent thickets and royalty stacking often occur, and discourage subsequent innovators – the larger number of licenses that have clauses on royalty sharing on the final product, the lesser the revenue for the innovator.[36]

Up until now, major cases where patents have blocked subsequent innovation and attracted public attention have not arisen in the biomedical sector,[37] but is the lack of a 'block buster' case pointing out to the absence of such behavior in the biomedical sector? Limited evidence that tests these concerns is available from USA, Switzerland and Germany. Walsh *et al.* conducted a survey of the biomedical sector in the USA, an interview method with 70 respondents supplemented mainly by archival data, which tried to test whether an 'anti-commons' can really be observed in the USA, and whether patent rights in the biomedical sector hinder innovation.[38] The study concludes that although problems of transaction costs, restricted access to research tools and royalty stacking exist, there is no real 'anti-commons' in biomedical research since parties are able to deal with these issues and '. . . IP on research tools, although sometimes impeding marginal projects, rarely precludes the pursuit of more promising ones'. The study underscores the importance of working solutions – like infringement, research exemptions, inventing around and invalidating patents in courts – in reducing the risks associated with the creation of an 'anti-commons' due to intellectual property protection on research tools. A German survey conducted on the issue comprised of 25 respondents and also uses a similar interview method.[39] This survey concluded that although royalty stacking is a real problem, research agreements are not usually hampered by the presence of intellectual property in the German biopharmaceutical sector, and working solutions and court resolution of disputes are common. Another common conclusion in both these studies was that firms in both countries admitted to avoiding taking on research projects where there are too many patents on research tools.[40]

2.3. Is there a Need for a Separate Framework for Developing Countries?

In which ways are the problems discussed in the previous sub-section different or more severe when one tries to assess the case of firms in technology follower countries? There

seem to be four main reasons that call for a differential framework to analyze the impact of intellectual property on biomedical innovation in technology follower developing countries, and require that an analysis on the impact of IPRs on biomedical innovation be necessarily conducted from an *ex-ante* decision-making perspective.

The first and most persuasive reason for a differential framework comes from the nature of innovation and the catch-up process itself. Catch up experiences of the present developed countries can be categorized into three stylized sets of observations:[41] (i) access to knowledge (of which access to technologies is a part of) and generation of knowledge locally have played a key role in economic development since the 18th century[42] and both usually depend on the capacity of domestic institutions for innovation; (ii) innovation is continuously encouraged by wide accessibility of already produced knowledge to society at low costs;[43] and (iii) intellectual property has been a very important institutional mechanism historically in enabling both access to existing knowledge and generation of new knowledge. It was used to achieve diffusion of innovations in local environments, without restrictions on reverse engineering and copying. This led to learning about the use of the innovation in different contexts, which in turn stimulated feedback improvements. Thus, most of today's state-of-the-art innovator countries passed through a spectrum of capability construction that is highly contested in intellectual property debates: reverse-engineering to incremental and feedback innovation to frontier innovations. In this context, can accumulated IPR positions by firms in developed countries that have a lead technological advantage be used to prevent serious competition from industries in technology follower countries in innovative activities at the frontier?

Even if this is not completely the case, given the oligopolistic market structure in global biomedical innovation and the widespread use of patents by firms for strategic reasons, is meaningful exchange hindered by the fact that firms on both sides do not have IP assets to trade that interest them mutually, in *quid pro quo* relationships? Even if there is a small chance that this could be true, its implications for global welfare need to be analyzed. In this context, the World Health Organization has warned against the fact that implications of patents on research tools may be much more drastic in technology follower countries: in addition to imposing transaction costs on research (of the kinds that can be resolved through 'working solutions' of various kinds), they can impede the transfer of existing tools and technologies completely.[44] Such an impediment to the transfer of existing tools and technologies to technology follower countries can prevent the development of innovative capabilities including knowledge-bases in the biomedical sector.[45] This problem is in many ways synonymous with the access to medicines problem that paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is seeking to resolve.[46] However, the impact of this issue is only just being felt and it may take some time until it mobilizes attention.

Second, the transaction costs that hinder the formation of efficient contracts in biomedical innovation can broadly be classified as search and information costs and bargaining and decision-making costs. Search and information costs refer to the set of costs that one incurs in order to obtain information on the various ways to conduct a transaction and to find the right set of partners in order to conduct the transaction. It also includes costs of getting informed about the contingencies that may materialize in the course of the contract. Similarly, bargaining and decision making costs refer to the costs of negotiating and reaching an agreement on the most important clauses of the contract. Usually, anticipating all contingencies and incorporating them into a contractual framework also entails costs.[47]

Negotiating access to technologies for firms in technology follower countries with firms who hold patents to these tools in developed countries will necessarily entail higher transaction costs related to both search and information, and negotiation and bargaining due to international nature of these transactions. Firms in technology follower countries could face bargaining anomalies that could result from monopolistic positions, information issues and transaction costs generated by the need to conclude licensing arrangements between firms/research institutes and universities across the globe. Additional market imperfections, caused by the fact that firms in technology follower countries operate in a context where legal uncertainty is widespread, often in terms of a lack of laws or institutional capacity to enforce corporate or intellectual property transactions, effectively calls into question 'working solutions' such as infringements and invalidating patents in courts.[48] The absence of well functioning legal frameworks impacts upon their ability to invoke effective working solutions to overcome transaction cost hurdles in securing access to technologies, which according to the US study on the issue is a very important resort among US firms in solving such problems.[49]

Third, what are the social costs of such an IPRs regime? Will a project be undertaken *ex-ante* even under the present IPRs regime? If patenting is excessive under this regime, then are its social costs offset by the diffusion of information through patents or through reduced incentives to litigate?[50] How would negotiation proceed without intellectual property protection and how does IPRs protection change bargaining thresholds of parties? That is, do we have more or less the same number of projects under alternate IPR regimes, all other things being constant? If not, how important are IPRs restrictions, when compared to other factors that affect firm-level decisions on taking up new innovation projects?

Another more general but important set of issues is raised by the nuanced relationship between patent policies and institutions, and the diffusion of knowledge and competition in different environments.[51] It is not only widely acknowledged now that the impact of patents on diffusion of information, inhibiting competition and promoting innovation is sector and context-specific but also that habits and practices of actors innovation systems can hinder/help leverage these effects.[52]

Several observations made in the US and German surveys support the need for a different framework for technology follower countries that looks deeper into these questions. The US survey itself, in several places, infers that the problems of royalty stacking, costs and delays in licensing owing to IP protection and upstream discover patents may be much more acute and even prohibitive for smaller firms with limited budgets. It is very likely that firms in other countries, especially developing countries, are more affected. These authors also conclude that the problem of intellectual property holders being able to limit access to upstream discoveries and promising research targets was generally considered to be manageable because if the research tool was critical, the interviewed firms would buy access to it.[53] Even if one accepts this observation, the extent to which this will hold for firms/research institutes in technology follower developing countries will depend on their ability to 'buy' access to important research tools. The emphasis on 'working solutions' to deal with these problems in the US and German surveys also calls for a more rigorous assessment of this issue on a larger scale, once again with a special emphasis on technology follower countries. Specifically, what will happen when a particular national legal regime does not provide for the same or similar 'working solutions' to be negotiated between parties in an efficient way? A final point that stands out is: 'what will be the implications for building innovative capabilities in firms in technology follower countries if they cannot

pursue research projects in areas where there are already too many patents on research tools?'

3. Biomedical Innovation in India: The Case of a Technology Follower

India is often cited as a prime example of an 'innovative developing country'[54] and offers a good case to analyze the impact of stronger patent rights on biomedical innovation. India has a thriving pharmaceutical sector with an expanding biotechnological base and is presently transitioning from a weaker IPR regime that promoted incremental and imitative innovation to a TRIPS compliant IPR regime. The remaining sections of this paper use empirical data to test the impact of patents on biomedical innovation in India. To answer the question: 'will a project be undertaken *ex-ante* even under the present IPRs regime?', this paper considers the earlier Indian IPR regime as a weaker alternative to the one presently prescribed by the TRIPS Agreement, in order to assess the impact of the TRIPS-compliant IPRs regime on choices of firms to pursue specific innovation portfolios, and its resulting impact on building innovative capabilities in biomedical sciences.

3.1. Innovation in Indian Pharmaceutical Biotechnology and the Impact of Patent Compliance

The Indian pharmaceutical sector is among the largest within developing countries, accounting for 8% of the global output in terms of volume and ranking 13th in terms of value in 2004.[55] The sale of retail formulations in the domestic market reached an estimated US$4.3 billion in the fiscal year 2003 and was dominated by Indian companies that held a market share of 75%.[56] Its major strengths include: a cost-competitive manufacturing base that extends to clinical studies, extensive skills in chemistry and process development, ability to manufacture over 50% of the bulk drugs needed for its pharmaceutical production activities locally, the emergence of a promising biotechnology industry, availability of local scientists and R&D personnel of a high scientific quality and a wide network of R&D.[57]

Indian compliance with the TRIPS Agreement has proceeded in several stages up until now. The Patents (Amendment) Act, 1999 introduced the mail box system and set up a system of exclusive market rights (hereafter, EMRs) to be retrospective from 1 January 1995 in conformity with the TRIPS Agreement. The Patent (Amendment) Act, 2002, introduced 64 changes to the Patent Act of 1970, the most important ones of these being the extension of patent term from 14 to 20 years, and the reversal of burden of proof from patent holder to alleged infringer.[58] The final set of changes to make India's patent regime comply with the TRIPS Agreement *in toto* were first contained in the Indian Patent Ordinance of 2004, that has now been replaced by the Indian Patent (Amendments) Act of 2005. The Indian Patent (Amendments) Act, 2005, seeks to complete India's full-scale compliance with the TRIPS Agreement. The Act has the effect of invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances, in order to make product patent protection of pharmaceuticals possible under Indian law. As a result, reverse engineering possibilities available to the pharmaceutical industry will only be limited to those drugs that are off-patent.

Section 47 of the original Patents Act of 1970 contains a research exemption for patented inventions (see Section 47 (3)). This section, which can be interpreted as applicable for both academic and commercial research, has been left unmodified by all subsequent amendments

to the patent regime, but two major changes introduced in the Amendments of 2002 affect the patenting of research tools for biomedical and biotechnological inventions in India. The Patent Act has extended the scope of patentable inventions to a method or process of testing during the process of manufacture, including those in biochemical, biotechnological and microbiological areas.[59] Section 3 of the Patent Act that deals with inventions that are not patentable was amended in 2002 to include any process for the diagnostic or therapeutic treatment of human beings or for a similar treatment of animals or plants (see Section 3(i)).

As a result of these provisions, biomedical research tools are patentable under Indian patent law. There are two exceptions to this. First, there is a research exemption for patented inventions (Section 47 (3) of the original Act), which can be interpreted to be applicable for both academic and commercial research, because the section contains no specific caveats. Second, medical, diagnostic and therapeutic kits/tools are not patentable *when* they are for the treatment of human beings or animals or plants.

3.2. Methodology and Variables

The empirical analysis is based on data collected during an industry survey of 103 pharmaceutical firms in India, between October 2004 and January 2005. The survey design was guided by a background country report of the Indian pharmaceutical sector, after which a range of semi-structured interviews with experts in the area of pharmaceutical innovation and intellectual property rights were conducted as the second step in order to help clarify the structure and content of the survey and to provide content validation to the survey questionnaire. The questionnaire was then administered to 103 firms ranked using data on export potential, R&D investments and annual sales from online databases on the Indian pharmaceutical sector, such as the India Infoline and Pharmabiz.

One of the key contributions of the survey results to analyzing emerging issues related to patent protection for pharmaceutical innovation and access to medicines in the Indian context is a categorization of firms in the Indian pharmaceutical sector into three main groups. This categorization, which was achieved on the basis of the empirical data collected, is very helpful in analyzing emerging firm strategies and their implications in detail. The first group of firms (hereafter, group 1) comprises large-scale pharmaceutical firms that are both subsidiaries of MNCs in India or wholly-owned Indian firms. The second group of firms (hereafter, group 2) comprises either generic manufacturers whose ability to do product development is limited or niche players who rely on innovative strengths to survive through activities such as contract research. The third and final group of companies (hereafter, group 3) are very small companies who mainly produce generic drugs for bigger Indian companies, both local and MNCs.[60] These three groups are representative of the Indian pharmaceutical sector, which amounts to approximately 6000 firms in total, engaged in the production of both bulk drugs and formulations.[61] Because this categorization is corroborated by their export potential, ability to invest in innovative activities and annual turnover, it helps pinpoint the extreme variance in industry structure because it embodies the vast differences among firms in terms of firm size, employment capacity, innovation potential, R&D investments and exports. The differences condition strategies for innovation and business, and have implications for access to medicines in depth.[62]

Out of the 103 firms surveyed as part of the empirical investigation, 31 belonged to group 1, 27 to group 2 and 44 to group 3. Data was collected over a period between 2000 and 2004, in order to be able to assess emerging constraints, firm strategies and the impact of

patenting over time. In addition to interviewing a cross-section of firms that participated in the survey, several other firms that were not part of the questionnaire survey were also interviewed during field work especially in the biotechnology sector to understand their main concerns and experiences on patent issues. The key informants consulted during field work were the Heads of Marketing and the Heads of R&D in each firm. Wherever the firms had their own intellectual property divisions, the heads of the intellectual property division were also interviewed.

4. Main Findings

The survey focused on several aspects of access to technologies for biomedical innovation in India. Among these, it addressed the question whether access to new technologies has become more difficult for firms since India began its phased out compliance with the TRIPS Agreement in 2002. Firms were asked to rank reasons for the increasing difficulties to access new technologies. Firms were also asked whether they have abandoned innovation projects because of IPR restrictions; and those that abandoned projects were asked to provide details. In the analysis, newer innovation projects represent opportunities for building innovative capabilities in the biomedical sector. Therefore, from a dynamic perspective, the larger number of useful innovation projects a firm has had to abandon owing to IPR restrictions, the larger the probability that the expansion of its technological capabilities has been restricted.

4.1. Descriptive Results

Will India's full-scale TRIPS compliance result in restricted access to technologies to the local pharmaceutical industry? To test this proposition, the survey posed the question whether firms face increased difficulties in accessing new technologies that are required for their activities after India started its phased compliance with the TRIPS Agreement over the past few years. A total of 43 firms felt that access to new technologies have become more difficult after India started implementing its compliance with the TRIPS Agreement. Of these, 12 belonged to group 1, 11 belonged to group 2 and 20 to group 3. Of the 43 firms that did face difficulties in accessing new technologies after India began complying with the TRIPS Agreement, only 28 firms admitted to having abandoned innovation projects because of patent protection. Of these, 11 belonged to group 1, 7 to group 2 and 10 to group 3 (see Table 1). Interviews with firm executives revealed that projects were abandoned mainly because (a) firms faced difficulties in terms of high costs for licensing and (b) firms

Table 1. Impact of TRIPS agreement on access to technologies

Firm group	Total no. of firms in group	More difficult access to technologies because of TRIPS		Abandoned innovation projects due to IPR restrictions	
		Number	Percentage	Number	Percentage
1	31	12	39% (12/31)	11	35% (11/31)
2	27	11	41% (11/27)	7	26% (7/27)
3	44	20	45% (20/44)	10	23% (10/44)
Total	$N = 102$	$N = 43$	100%	$N = 28$	100%

Source: WHO-INTECH survey conducted by author, 2005.

Table 2. Reasons for difficulties in accessing new technologies after India's TRIPS compliance

Firm group/Effect	Too many patents on research inputs needed for innovation	Restricted access due to contractual difficulties	Royalty stacking in licensing contracts	High licensing fees
1	3.17 (12)	3.33 (12)	2.33 (12)	3.33 (12)
2	3.91 (11)	3.64 (11)	2.55 (11)	3.91 (11)
3	3.35 (20)	3.55 (20)	2.79 (19)	3.58 (19)
Average mean/firm total	3.44 (43)	3.51 (43)	2.60 (42)	3.60 (42)

Note: The rating is the mean score for each group of firms, with 1 = weakest and 5 = strongest, any rating above 2.5 is an important constraint. The figures in parentheses represent the number of firms.
Source: WHO-INTECH field survey conducted by author, 2005.

realized *ex-post* that the results of their innovation projects would infringe patents filed for by competitors on the same compounds/processes (interviews).

The survey also asked the firms to identify factors responsible for difficulties in accessing new technologies. The respondents were asked to assign a score to each one of the reasons contained in Table 2 from 1 (weakest) to 5 (strongest). As Table 2 shows, all reasons from significant to very significant (above 2.5), with royalty stacking being a reason that is relatively less important than multiple patents, restricted access owing to contractual difficulties and high licensing fees. Furthermore, the survey response to this question also shows that group 2 firms are much more sensitive to the increasing number of patents, restricted access and the high licensing fees involved in carrying out incremental innovations as a result of India's TRIPS compliance.

4.2. The Model

These findings, albeit indicative of the relationship between access to technology issues and the likelihood of abandoning innovation projects, are merely descriptive. An empirical model that explains the probability of firms' decisions to abandon innovation projects was constructed using probit technique. The definition of variables is contained in Table 3.

The model is described as follows:

$$d_i^* = \beta' x_i + \varepsilon_i, \quad i = 1, \ldots, N \tag{1}$$

and

$$d_i = \begin{cases} 1 & \text{if } d_i^* > 0 \\ 0 & \text{if } d_i^* \leq 0 \end{cases} \tag{2}$$

The *latent* (unobserved) variable d_i^* captures economic or strategic reasons of firm i to abandon innovation which is a function of observed explanatory variables x_i and other unobserved factors that are summarized in ϵ_i. If the economic reasons cross a certain threshold $d_i^* > 0$, d_i is observed to be 1, meaning that firm i has abandoned innovation projects, otherwise it is observed to be 0 meaning that the firm has continued to perform

Table 3. Variable definitions

Variable	Definition
Gvt. Subsid 2000–2004	Indicator with value 1 if a firm receives any government assistance over the period 2000–2004
Employment in 2004	Total employment in 2004 expressed in full time equivalent (fte); a log transformation is used in the regressions
R&D intensity in 2004	The share in total sales of R&D expenditures in 2004; a log transformation is used in the regressions
Past continuous R&D performance	Indicator with value 1 if a firm has positive R&D expenditures over the period 2000–2003
Past occasional R&D performance	Indicator with value 1 if a firm has positive R&D expenditures in any year between 2000–2003
Product innovators	Indicator with value 1 if a firm has carried out new product development
Process innovators	Indicator with value 1 if a firm has carried out new process development
Exporting firms	Indicator with value 1 if a firm exports
Technology licensing	Indicator with value 1 if innovation source from technology licensing is fairly strong, strong or very strong
Joint venture R&D	Indicator with value 1 if innovation source from joint venture R&D is fairly strong, strong or very strong
Hiring skilled employees	Indicator with value 1 if innovation source from hiring skilled workers is fairly strong, strong or very strong
Royalty stacking	Indicator with value 1 if royalty stacking is deemed to be fairly strong, strong or very strong reason of IPR restriction
Proliferation of patents	Indicator with value 1 if proliferation of patents on inputs needed is deemed to be a fairly strong, strong or very strong reason of IPR restriction
Restricted access to technology	Indicator with value 1 if restricted access to upstream technology is deemed to be a fairly strong, strong or very strong reason of IPR restriction
Very high licensing fees	Indicator with value 1 if very high licensing fees are deemed to be a fairly strong, strong or very strong reason of IPR restriction
Total sales in 2004	Total sales in 2004; the log-transformed variable is included in the regressions
Financial constraint	Indicator with value 1 if financial support is deemed to be a fairly severe, severe or very severe constraint to deal with new IPR challenges
Firms in cluster 1	Indicator with value 1 if it belongs to cluster 1
Firms in cluster 2	Indicator with value 1 if it belongs to cluster 2
Firms in cluster 3	Indicator with value 1 if it belongs to cluster 3

innovation projects. To estimate the model as described in equations (1) and (2), we assume the errors ϵ_i to be identically and independently distributed (i.i.d) standard normal. The loglikelihood function is derived as:

$$\ln L = \sum_{i=1}^{N} \ln \Phi[(2d_i - 1)\beta' x_i], \tag{3}$$

where Φ is the standard normal cumulative distribution function. The probit model is estimated by including into the vector x_i all the variables of Table 3, but R&D intensity as regressors, which results in the *general* model. The effort to remove the explanatory variables that are not significant results in the *restricted* model. This latter model is tested against the more general one using a likelihood ratio test where the null hypothesis is that of the joint nonsignificance of these explanatory variables. With a $x^2_{(13)} = 10.98$ and a p-value of 0.612, the null hypothesis is not rejected at any standard significance level thereby leading us to reject the general model in favor of the restricted one. The results of this model are as shown in Table 4 below.

The term 'innovation projects' is construed in the model to be in accordance with the discussion in Sections 1 and 2 of the paper. All projects using those firms that are seeking to expand their innovative activities in ways that enhance their learning skills, expand knowledge base and increase competitiveness both locally and globally, are termed innovative projects. This includes R&D but also includes all other forms of activities through which firms access knowledge and technologies in order to progress along the learning curve. All the 103 firms that participated in the survey are seeking to enhance their innovative capacities to scale up the global innovation frontier.[63]

Table 4. Probit ML estimates of the probability of abandoning innovation projects and likelihood ratio test

	Coefficient (Std. Err.)		Coefficient (Std. Err.)	
Variable	General model		Restricted model	
Gvt. Subsid 2000–2004	1.158**	(0.395)	1.067**	(0.352)
Employment in 2004 (in log)	−0.770*	(0.327)	−0.462†	(0.237)
Past continuous R&D perf.	−0.365	(0.447)	–	–
Past occasional R&D perf.	−0.308	(0.519)	–	–
Product innovators	0.785	(0.490)	–	–
Process innovators	−0.890†	(0.457)	−0.650*	(0.315)
Exporting firms	0.039	(0.437)	–	–
Technology licensing	−0.053	(0.365)	–	–
Joint venture R&D	0.375	(0.387)	–	–
Hiring skilled employees	−0.310	(0.440)	–	–
Royalty stacking	0.219	(0.553)	–	–
Proliferation of patents	−0.997	(0.926)	–	–
Restricted access to tech.	0.874	(0.610)	1.006**	(0.303)
Very high licensing fees	1.126	(1.090)	–	–
Total sales in 2004 (in log)	0.092	(0.309)	0.393*	(0.191)
Financial constraint	−0.321	(0.629)	–	–
Firms in cluster 1	1.637†	(0.863)	–	–
Firms in cluster 2	0.250	(0.560)	–	–
Intercept	3.128†	(1.751)	0.227	(0.978)
Number of firms	103			
Log-likelihood	−41.552		−47.044	
Likelihood ratio test	$x^2_{(13)} = 10.98$, p-value = 0.612			

Significance levels: †10%; *5%; **1%.

The model retained four variables – government subsidies between 2000 and 2004, process innovation, restricted access to technologies and total sales 2004 (log). The probability of abandoning innovation is positively and significantly affected by government subsidies and restricted access to upstream technology at 1% level of significance, and total sales at 5% level of significance. Being a process innovator and total sales (log) affect negatively and significantly the probability of abandoning innovation projects at 5% and 10% significance levels respectively.

The result on *Restricted access* is also supported by descriptive data gathered in the survey, contained in Table 2. Firms repeatedly iterated the problems of contractual difficulties that pointed to transaction cost issues that arise especially in transnational contexts (Indian firms need to license research tools from foreign firms). In addition to the problems posed by the international nature of the transaction, this also points attention to another potential issue: such license transactions may be failing because although they are important for the Indian firm, they may be only of marginal importance to the foreign counterpart who holds the patent. Firm executives also confirmed abandoning research projects where there were too many existing patents, a finding that is in line with both the US and German surveys. At the same time, executives also admitted to the difficulties in branching out to specific areas of research because of the problems of obtaining licenses or of too many existing patents that discourage innovation plans, thus clearly emphasizing the issues for firms in technology follower countries trying to expand innovative capabilities and knowledge bases.

Several firms in groups 1 and 2 that face difficulties in forging good technological alliances with firms abroad tend to rely on abandoning innovation but also simultaneously grope for support within the system, especially in terms of governmental incentives, in order to expand their innovation activities and survive. This explains the result on governmental subsidies and the probability of abandoning innovation projects in the model.

Being a *process innovator* is negative and significantly associated with the probability that a firm abandons innovation projects. Firms that rely on process innovation in the Indian pharmaceutical sector predominantly perform generic activities, whereas firms that focus mainly on product innovation or both on product and process innovation are those that are trying to move away from traditional chemical synthesis into innovative niches or new product development. Therefore, the latter group of firms faces a greater burden of securing access to new technologies, and being a process innovator is negative and significant for the probability of abandoning innovation.

The result on total sales (log) is striking, because it seems to suggest that firms with higher sales abandon innovation projects, but explains the state of flux in the sector presently. Some firms have been very successful and have had major breakthroughs albeit with less employees. A good example is Matrix Laboratories, which rose very fast between 2000 and 2005 as a result of its success in developing innovative alternate processes for production of active pharmaceutical ingredients. However, such firms are curtailed by the low general manpower and other infrastructure from pursuing negotiation and licensing activities, and are also more prone to sudden shocks.[64] This contrasts the result that firms with higher total employment (log) in 2004 are more unlikely to abandon innovation projects. Firms with higher total employment (2004) are some of the most sophisticated firms in the sector, and they have grown consistently over time with higher total employment being directly proportional to higher sales. They not only have very good IPR departments and several hundred people employed within them, but they also have the resources to conduct trans-border transactions/negotiations effectively in cases where the technology in question is

Table 5. Marginal effects on the probability of abandoning innovation projects: restricted model

Variable	Slope	(Std. Err.)
Gvt. Subsid 2000–2004	0.371**	(0.127)
Employment in 2004 (in log)	−0.138†	(0.071)
Process innovators	−0.202*	(0.100)
Restricted access to tech.	0.321**	(0.095)
Total sales in 2004 (in log)	0.117*	(0.058)

Significance levels: †10%; *5%; **1%.

very important.[65] They are also in a series of collaborative research ventures with global pharmaceutical firms,[66] and possess bargaining power and strategic assets that could interest their global partners. Another explanation for the contrasting results of these two variables is that the propensity to innovate comes from declining profits. Firms that are threatened by a loss of sales or loss of profit (which is especially difficult to withstand if the firm size is large) are driven to seek newer innovation venues.

4.2.1. Marginal effects.

Since the coefficients in Table 4 do not measure the sensitivity of the outcome (probability of abandoning innovation projects) being 1 with respect to changes in explanatory variables i and x, it is important to calculate the marginal effects that measure this sensitivity. Table 5 reports the marginal effects on the probability of abandoning innovation projects. Switching from the non-subsidized to the subsidized status is associated with the probability of abandoning innovation projects by 0.371. Similarly, increasing the difficulties in access to upstream technology by one unit results in the probability of abandoning innovation projects of 0.321, and increasing the likelihood of being a process innovator decreases the probability of abandoning innovation projects by 0.202.

5. Conclusions

This paper has tried to identify reasons that call for the development of more comprehensive frameworks as well as collect more systematic data to assess the impact of patents on biomedical innovation in technology follower countries. The analysis has shown that four sets of issues are very important in a framework that looks at the impact of the TRIPS Agreement on biomedical innovation from a technology follower developing country perspective: the nature of innovation and catch-up process and the possibility that accumulated IPR positions result in impeding access to research tools for firms in technology follower countries, the kinds of bargaining anomalies that could result from monopolistic positions, information issues and other transaction costs in international licensing arrangements between firms/research institutes and universities, the impact of alternative intellectual property rights regimes (that is, a TRIPS compliant regime vs a different one) on the number of innovation projects undertaken, and lastly, the impact of differential patent policies and institutions on knowledge flows, diffusion of innovation and habits and practices of actors in innovation systems.

To assess whether we have more or less the same number of projects under alternate intellectual property rights regimes (that is, TRIPS compliant regime vs a different one), this paper considered the earlier Indian IPR regime as a weaker alternative to the one presently prescribed by the TRIPS Agreement, in order to assess the impact of the TRIPS-compliant IPRs regime on choices of firms to pursue specific innovation portfolios and the resulting impact on building innovative capabilities in biomedical sciences. All other things being constant, the Indian case analyzed in this paper shows that patent protection in the biomedical sector has a negative impact on the number of projects pursued under a TRIPS compliant regime. Newer innovation projects represent opportunities for building innovative capabilities in the biomedical sector. From a dynamic perspective, the larger number of useful innovation projects a firm has to abandon owing to IPR restrictions, the larger the probability that the expansion of its technological capabilities is restricted. This requires a more detailed look and a more rigorous analysis in the coming years, as and when more information on the Indian industry becomes available.

The model developed in the paper using empirical data from the Indian pharmaceutical and biotechnology sector shows that among the four determinants of a firm's probability of abandoning useful innovation projects, restricted access to upstream technology because of contractual difficulties is a factor that is highly significant (at 1%). The marginal effects of each one of these variables has been calculated in the analysis, in order to see how each variable is likely to influence a firm's probability of abandoning innovation, and how important IPR restrictions are, when compared to other factors that affect the building of innovative capabilities in technology follower developing countries. This analysis reveals that restricted access to upstream technologies as a result of contractual difficulties was the variable that is likely to have maximum impact on a firm's decision to abandon innovation projects. If a firm increased its chances of high restricted access to technology by one unit, it was likely to increase its chance of abandoning innovation by 0.320 points – this was much more than the computed effect of other variables that affected a firm's likelihood of abandoning innovation projects in the Indian industry.

Given the extreme significance of a global IPR regime in facilitating technological catch-up processes, it seems important to gather as much empirical data as possible on the subject from countries at different stages of development. Several countries are yet to comply with the TRIPS Agreement or are in the process of doing so and such cases may prove to be good sources of data on assessing TRIPS vs alternate IPR regimes.[67] To study this problem and its impact systematically in developed as well as technology follower developing countries, more unified research methodologies may be required. When existing evidence from the USA, Germany and Switzerland, and now India, are consulted on the issue, the impact of IPRs on biomedical innovation seems to be divergent. It appears that differences in research methodologies (interview method vs firm-level data collection) are the main reason for contrasting empirical evidence on this issue until now.[68]

The same/similar sets of patent policies and institutions can have different impacts on knowledge flows, diffusion of innovation and habits and practices of actors in different systems of innovation. These inter-linkages need to be assessed in country-specific contexts. Taking the TRIPS level of intellectual property protection for granted, technology follower countries should look at reducing the problem of restricted access through appropriate design of patent regimes. Analysis of these inter-linkages should take into account the nuanced relationship between patent policies on creating widespread technological interdependence in the biomedical sector. Such technological interdependence does not necessarily have

to be the result of policies that dictate broad patent scope. Even in regimes where patent policy dictates that patents are granted only on fewer claims and the claims themselves are interpreted more narrowly, there is a possibility that this generates more patents per product/technology thereby leading to as much technological interdependence as patent policies that construe and grant broad patent claims.[69] This calls for a very sound assessment of patent scope issues within every system of innovation. Additionally, solutions such as extended disclosure requirements in patent laws and increased pre-grant procedures that have been successful in inducing technological spillovers between firms in other sectors should be considered.[70]

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5. Heller & Eisenberg, *op. cit.*, Ref. 4; Heller, *op. cit.*, Ref. 4; R. Eisenberg, 'Bargaining over the transfer of proprietary research tools: is this market failing or emerging, in: R. C. Dreyfuss, D. L. Zimmerman & H. First (Eds) *Expanding the Boundaries of IP: Innovation Policy for the Knowledge Society* (Oxford, Oxford University Press, 2001).

Q9

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30. *Ibid.*, p. 230.
31. *Ibid.* and OECD, *op. cit.*, Ref. 3. Eisenberg summarizes these as the main issues that were significant during the investigation of the Working Group on Research Tools, National Institute of Health, USA, 1998, which investigated difficulties encountered by researchers in obtaining access to proprietary research tools in biomedical research.
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33. See also in this context O. Granstrand, *The Economics and Management of Intellectual Property* (Cheltenham, Edward Elgar, 2000).
34. Cohen *et al.*, *op. cit.*, Ref. 1.
35. OECD, *op. cit.*, Ref. 3.
36. Royalty stacking refers to a situation where each earlier innovator grants access to his/her product in return for a royalty on the new innovation. The greater number of earlier patents that need to be licensed to proceed with innovation, the larger the number of royalty agreements that get 'stacked' on to the yet-to-be-discovered product.
37. See for example the case of the digital video compression standard MPEG 2, where patent pools have been successful in solving problems of patent thickets and 'stacking' licenses, or the case of 'golden rice' in agricultural biotechnology.
38. J. P. Walsh, A. Arora & W. M. Cohen, The patenting of research tools and biomedical innovation, in: W. M. Cohen & S. A. Merrill (Eds) *Patents in the Knowledge-Based Economy* (Washington, DC: National Academy Press, 2003), pp. 285–340. The sample is a mix of universities and firms. Seventy interviews were conducted with IP attorneys, business managers and scientists from 10 pharmaceutical firms, 15 biotechnology firms as well as university researchers and technology transfer officers from six universities and finally, patent lawyers, government and trade association personnel.
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48. Legal uncertainty can refer to any or all of the following three possibilities: (a) lack of laws and institutions to suitably enforce corporate and intellectual property transactions, or (b) laws that exist to govern corporate and intellectual property transactions, but they do not clearly prescribe rights, obligations and remedies; or (c) unstable political or legal situation in the country, as a result of which a 'new' legal situation may emerge at any time after concluding the contract.
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50. Cohen *et al.*, *op. cit.*, Ref. 2.
51. Granstrand, *op. cit.*, Ref. 33.
52. Cohen *et al. op. cit.*, Ref. 2, found in a comparison of R&D labs in the manufacturing sectors between Japan and USA that appropriability conditions depend on cross-national differences in policy and institutional

environments. Hence, patents played a larger role in diffusion of information across rivals in the Japanese industry than in the USA and this was found to be due to their respective patent systems.

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63. See Gehl-Sampath, 2005, *op. cit.*, Ref. 60, and Gehl-Sampath, 2006, *op. cit.*, Ref. 60.
64. This is the reason why a firm like Matrix Laboratories, which rose quickly from being a group 2 to a group 1 firm by 2006, was acquired by another company despite its success.
65. Such firms have also shown that they are capable of fighting sophisticated patent disputes in the EU and the USA (see Gehl-Sampath, 2006, *op. cit.*, Ref. 60, and Grace, 2005, *op. cit.*, for examples).
66. Gehl-Sampath, 2006, *op. cit.*, Ref. 60.
67. Because several developing countries have only recently complied with the TRIPS Agreement (and several LDCs are yet to comply as a result of the extension granted to them under the Doha Agreement on the TRIPS Declaration and Public Health until 2016), data that compares a pre-TRIPS scenario to a post TRIPS is a very useful tool for analysis.
68. The samples considered in the US and German surveys are mixed and relatively small, with respondents from both the private and public sector. Furthermore, both surveys are descriptive; descriptive surveys usually need to be corroborated by firm-level evidence. At the same time, several of the results obtained from the Indian survey and presented in this paper are very similar to the Swiss survey of the biotechnology industry, which was also a firm level investigation.
69. Cohen *et al.*, *op. cit.*, Ref. 2, p. 1357; Granstrand, *op. cit.*, Ref. 33.
70. Cohen *et al.*, *op. cit.*, Ref. 1.